

### **REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

#### **Claim Amendments**

Claim 1 has been amended to recite that the crystalline aliphatic polyester comprises glycolic acid homopolymer or a copolymer of glycolide with at most 10 wt% of lactide.

Support for this amendment is found on page 10, lines 11-15, and page 11, lines 6-11 of the specification.

#### **Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 1-7 and 9-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states that the specification does not provide proper antecedent basis for “said crystalline aliphatic polyester comprises glycolic acid homopolymer or a copolymer of at least 90 wt% of glycolide.”

This rejection has been rendered moot by the above-discussed claim amendments. Applicants do not acquiesce to the Examiner’s position, but have amended the claim in order to expedite allowance of the application.

The language of amended claim 1 is explicitly supported by the specification. Specifically, page 10, lines 11-15 of the specification indicates that the glycolic acid copolymer may be synthesized by copolymerizing glycolide and lactide. Page 11, lines 6-10 of the specification describes that it is preferred to use cyclic compounds, such as lactide, in a proportion of at most 10 wt%.

Accordingly, as the specification clearly provides support for Applicants’ claims, it is respectfully requested that the written description rejection be withdrawn.

**Consideration After Final Rejection**

Although this Amendment is presented after final rejection, the Examiner is respectfully requested to enter the amendments and consider the remarks, as they place the application in condition for allowance.

**Patentability Arguments**

The patentability of the present invention over the disclosure of the reference relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

**Rejection Under 35 U.S.C. § 102(b)**

Claims 1-7 and 9-12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shiiki et al. (EP 0 925 915).

**The Position of the Examiner**

The Examiner takes the position that Shiiki et al. disclose a gas barrier multi-layer hollow container with a polyglycolic acid layer. The Examiner further states that the aliphatic polyester can be comprised of 98 wt% of glycolide and 2 wt% lactide.

The Examiner admits that the reference fails to disclose: (1) that the aliphatic polyester has a crystal melting point higher by at least 3°C or 5 °C than an unstretched product, (2) the main dispersion peak temperature, (3) the sub-dispersion peak temperature, and (4) the orientation degree. The Examiner contends that these properties are inherent to the structure in the prior art, since the reference teaches an invention with a substantially similar structure and chemical composition to the claimed invention. The Examiner asserts that the burden is on Applicants to prove otherwise.

**Applicants' Arguments**

This rejection is respectfully traversed for the following reasons.

In order to anticipate Applicants' claims, it is necessary that each and every limitation of the claims be found, either expressly or inherently, in a single reference. See MPEP 2131. As discussed above, the Examiner admits that Shiiki et al. fail to teach many of Applicants' claim limitations, and the Examiner has relied on inherency to meet these limitations.

The following discussion regarding inherency is provided in MPEP 2112 (IV):

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). (Emphasis added.)

Thus, for inherency to be properly relied upon, it must be shown that the missing limitations (i.e., crystal melting point differential, peak temperatures and orientation degree) are necessarily present in the product of the prior art. Applicants respectfully assert that this is not the case, and therefore the anticipation rejection is improper.

Shiiki et al. disclose a "mutli-layer blow molding process" in paragraphs [0052] and [0054]. However, Shiiki et al. fail to disclose intense stretching, which requires both (1) a stretching temperature just above T<sub>g</sub> (glass transition temperature), and (2) a large stretching ratio.

Applicants respectfully direct the Examiner's attention to the Examples and Comparative Examples of the specification. Table 1 (page 24 of the specification) demonstrates that the stretched films of Comparative Examples 1-3, which were obtained through stretching at ratios of 3 x 3 times at 45-80 °C, and the stretched films of Comparative Examples 4 and 5, which were obtained through stretching at ratios of 4 x 4 times or 4.5 x 4.5 times, respectively, caused an increase in the crystal melting point (T<sub>m</sub>) of only 1-2 °C compared to Comparative Example 6, which is unstretched. On the contrary, Examples 1-4, which were obtained through stretching at ratios of 4 x 4 or 4.5 x 4.5 times, at a stretching temperature of 45 or 60 °C, exhibited an extremely remarkable increase in T<sub>m</sub> of 8-9 °C compared to Comparative Example 6 (unstretched).

Thus, Examples 1-4 fulfill the requirement of Applicants' claim 1, i.e., that the stretched product has a  $T_m$  higher by at least 3 °C than the unstretched product. On the contrary, Comparative Examples 1-5 fail to full this requirement. This comparison demonstrates that simply because Shiiki et al. teaches a gas barrier mutli-layer hollow container with a polyglycolic acid layer, where the aliphatic polyester can be comprised of 98 wt% of glycolide and 2 wt% lactide, does not mean the stretched product necessarily fulfills the limitations of Applicants' claims. Thus, the Examiner's reliance on inherency is untenable, and the rejection should be withdrawn.

Furthermore, in Example 4 of Shiiki et al. (the only example of a cold stretch blow molding process for PET/Adh/PGA/Adh/PET laminate in the reference), a stretched temperature of about 85 °C and a stretching ratio of 3 x 2 times is used. Applicants note that the temperature is higher than the highest temperature in the Comparative Examples of the specification (i.e., 80°C), and the ratio is smaller than the smallest stretching ratio in the Comparative Examples of the specification (i.e., 3 x 3 times).

Thus, in view of the comparison discussed above (based upon the experiments in Applicants' specification), one of ordinary skill in the art would not expect the teachings of Shiiki et al. to result in the stretched product of Applicants' claims.

Accordingly, Applicants respectfully assert that the subject matter of the claims is patentable over Shiiki et al., and the rejection based thereon should be withdrawn.

**Note regarding Supplement to Information Disclosure Statement**

In item 8 on page 5 of the Office Action, the Examiner refers to the Supplement to Information Disclosure Statement filed February 17, 2009. The Examiner correctly indicates that the supplement refers to eight references discussed in the IDS filed December 22, 2008. The Examiner then states that the IDS dated December 22, 2008 only references three foreign patent documents.

Applicants kindly note that although the PTO-1449 Form attached to the IDS of December 22, 2008 only lists three references, item 3 on pages 2 and 3 of the IDS (the document itself) lists eight references. The remaining five references (which were not cited on the PTO-

1449 Form of December 22, 2008) were previously cited on the PTO 1449 Form submitted with the IDS of March 18, 2005.

**Conclusion**

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

Daisuke ITOH et al.

/Amy E. Schmid/

By 2009.08.20 15:38:05 -04'00'

Amy E. Schmid  
Registration No. 55,965  
Attorney for Applicants

AES/emj  
Washington, D.C. 20005-1503  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
August 20, 2009